

**NATIONAL ENVIRONMENTAL
LABORATORY ACCREDITATION
CONFERENCE**

AD HOC TRANSITION COMMITTEE

REPORT FROM THE NELAC AD HOC TRANSITION COMMITTEE

BACKGROUND:

The National Environmental Laboratory Accreditation Conference is a voluntary association of states, federal agencies, and tribal governments established to develop national standards for environmental laboratory accreditation. Established in 1995, NELAC has up to this point been involved in creating an organizational framework and writing accreditation standards. Final adoption of all standards is expected to be complete in July of 1997, following the third annual meeting of NELAC (NELAC III). At that time, the focus of NELAC will shift from standards development to implementation and actual operation of the program.

How NELAC is implemented and managed in this early stage is critical to the long-term success of the program. Therefore, it is essential that NELAC members and NELAP program staff at EPA headquarters work together to develop an effective plan for implementing NELAC standards nation-wide.

PURPOSE:

The role of the Ad Hoc Transition Committee is to recommend a plan for implementation of NELAC standards to the Board of Directors. This plan will identify potential issues and policy concerns and make recommendations to the Board for resolution.

MEMBERS:

States: Ms. Carol V. Batterton, TX, Chair, Dr. Charles Brokopp, UT, Vice Chair, Mr. John P. Anderson, IL, Ms. Pauline Bouchard, MN, Dr. Eldert C. Hartwig, Jr. FL, Dr. Kenneth W. Jackson, NY

EPA: Mr. Stephen Clark, OW, Mr. Ted Coopwood, NELAP, Ms. Jeanne Mourrain, NELAP

Laboratories: Dr. Andy Eaton, Montgomery-Watson Labs, Dr. J. Wilson Hershey, Lancaster Laboratories, Mr. Jerry Parr, Quanterra, and Ms. Ann Rosecrance, Core Laboratories

ISSUES AND RECOMMENDATIONS:

- I. The initial approval of accrediting authorities should occur simultaneously in accordance with the timelines shown on Attachments 1 and 2.

Discussion:

One of the greatest concerns about NELAC implementation expressed by states and laboratories has to do with the initial onslaught of laboratories which would be seeking accreditation. If applications from state and other federal agencies seeking to become accrediting authorities are processed on a “first in, first out” basis, there is concern that it could lead to one or two states being inundated with applications from laboratories from all over the nation, resulting in delays in processing times. By simultaneously processing the initial applications for accrediting authorities, it reduces the likelihood that one accrediting authority will have excessive numbers of applications to approve initially, and that laboratories accredited in some states will have a competitive advantage. This proposal also calls for:

- a) States to declare their intent with regard to becoming an accrediting authority by June 15, 1997 which allows EPA to plan for adequate resources,
- b) Potential accrediting authorities to submit applications by December 1, 1997,
- c) NELAP to process and approve all applications from potential accrediting authorities by April 15, 1998, and
- d) NELAP approval of initial accrediting authorities granted by June 15, 1998

In order for these timelines to be met, several other activities must occur within the same timeframe:

- a) Finalize draft application form for accrediting authorities
- b) Identify and train NELAP assessment teams
- c) Finalize checklist for application review
- d) Finalize checklists for laboratory on-site inspection

The first three activities are the responsibility of the NELAP Director’s office with assistance from the Accrediting Authority Committee. The On-Site Assessment Committee will complete item (d).

Dr. Charles Brokopp coordinated the effort to survey states regarding their intent to seek NELAC recognition. The survey indicated that a total of 36 states plan to apply for recognition as NELAC accrediting authorities. Eight states indicated they will apply for NELAC recognition as accrediting authorities at the first opportunity. Another 13 states plan to apply prior to October 1998 and 19 states will apply after October 1998. Survey results are shown in Attachment 3.

- II. The first round of NELAC accreditation of laboratories by accrediting authorities should also occur simultaneously.

Discussion:

Again, there was concern about the competitive advantage gained by accredited laboratories if only a handful had early NELAC accreditation. Once the initial accrediting authorities have been approved, they, along with the NELAP director, should negotiate a mutually acceptable timeline for issuing accreditations simultaneously.

Once the accrediting authorities have received the initial round of applications from laboratories, it may be necessary to revise the timeline. If a given accrediting authority receives an excessive number of applications, there should be the option to shift some of these applications to another NELAC accrediting authority in order to maintain a reasonable timeframe for issuing accreditations.

In order for this process to occur, several other activities must be completed:

- a) Laboratory assessor training manuals and courses must be completed by June 1998;
- b) Assessor checklists must be completed by June 1998; and
- c) NELAC database must be operational

The committee members representing laboratories also expressed concern that federal and state agencies presently had significant differences in accreditation requirements such as differences in quality control requirements and particular methods. Current draft language in the Quality Systems Chapter appears to allow these differences to continue. If unaddressed, this situation could jeopardize reciprocity. The committee will address these concerns with the Quality Systems Committee before NELAC III.

- III. Prior to the designation of NELAP approved proficiency test (PT) sample providers as required by Chapter 2, accredited labs should be allowed to continue using existing PT sample providers. However, in the interim, frequency of PT sample analysis as required by Chapter 2 must be met.

Discussion:

Chapter 2, as currently proposed, requires NELAC accredited labs to obtain PT samples from approved providers. The process of setting up the PT oversight body and approving providers likely will not occur prior to the issuance of the first round of NELAC accreditations. Therefore, the committee recommends that laboratories be allowed to continue using present sources of PT samples, but to supplement from other sources as necessary to meet the frequency requirements of Chapter 2. Maintaining the frequency requirements specified in Chapter 2 is necessary to assure reciprocity. Accrediting authorities will be required to explain their provisions for proficiency testing as a part of the accrediting authority approval process.

- IV. The Ad Hoc Transition Committee should receive additional comments on implementation issues at NELAC III.

Discussion:

During the course of the committee's discussions, it became clear that several issues warranted additional discussion and input. These topics include:

- 1) State supplemental requirements with respect to reciprocity
- 2) Guidance for states to complete application process
- 3) Additional concerns regarding implementation
- 4) Scope of program
- 5) Dual programs
- 6) Assuring auditor proficiency

V. Response to comments

Discussion:

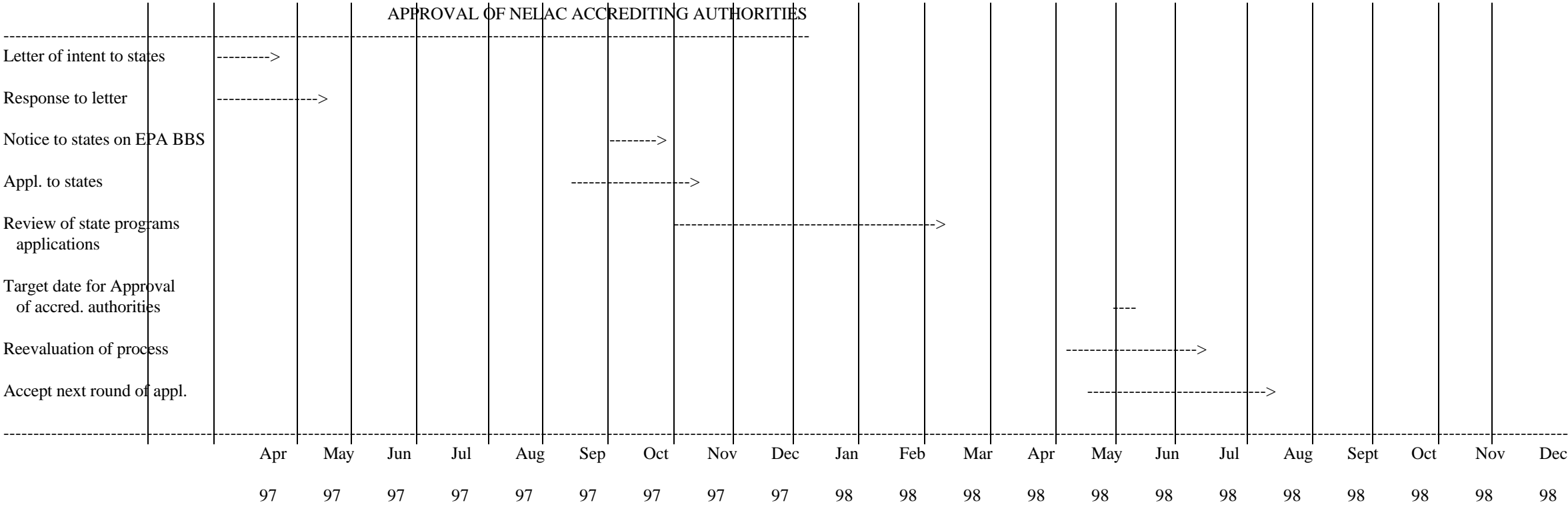
A number of comments have been received regarding NELAC implementation. Those comments are attached and specific responses to these concerns are given in Attachment 4.

APPROVAL PROCESS FOR NELAC ACCREDITING AUTHORITIES

TASK	TARGET DATE	ASSIGNED TO
1. Send "letter of intent" to states/federal agencies asking if and when they will seek recognition as NELAC accrediting authority	May 1, 1997	Charles Brokopp
2. States respond to letter of intent	June 15, 1997	States/Charles Brokopp & Carol Batterton monitor responses
3. Accrediting authority committee develops application form and guidance materials	Final draft at NELAC III	John Anderson
4. Meet with all potential accrediting authority applicants at NELAC III	July 28-31, 1997	Jeanne Mourrain, Carol B, Charles Hartwig, Charles Brokopp, John Anderson, etc.
5. Notice on EPA BBS that applications will be available within 30 days	September 1, 1997	Jeanne Mourrain/Ted Coopwood
6. Letter to potential accrediting authorities with applications forms - due in 60 days	October 1, 1997	Jeanne/Ted
7. Application forms due from accrediting authorities <ul style="list-style-type: none"> - Assessment teams identified & trained - Checklist for application review finalized 	December 1, 1997	Jeanne/Ted

APPROVED PROCESS FOR NELAC ACCREDITING AUTHORITIES (Cont'd)

TASK	TARGET DATE	ASSIGNED TO
8. Review and process state applications - Completeness review - Technical review - On-Site audit - Recommendation to NELAP Director	April 15, 1998	Jeanne, Ted, and assessment teams
9. NELAP Director issues approval of accrediting authorities	June 1, 1998	Jeanne
10. Evaluate process and set target date for next batch applications	July 1998	AARB, BoD, Jeanne, Ted



NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE (NELAC)

Summary of Intent Survey - June 27, 1997

The National Environmental Laboratory Accreditation Conference (NELAC) has developed standards for national environmental laboratory accreditation. Many of the current programs that accredit environmental laboratories have contributed to the development of these standards and are looking forward to becoming recognized as a NELAP accrediting authority. A survey of the programs that accredit environmental laboratories was conducted during June 1997 by the Utah Department of Health to determine the intent of programs to request recognition by NELAP. The results of the survey will be used by NELAC to plan for the recognition of accrediting authorities.

A brief questionnaire was sent to each of the designated NELAC representatives to obtain information on the intent of laboratory accreditation programs within their jurisdiction to pursue recognition by NELAP. The questionnaire was distributed by mail or fax and contained instructions for the recipient to forward the questionnaire to the appropriated person for completion if the recipient was not able to respond. A representative from states that do not have an officially designated NELAC representative was also contacted to obtain a response to the survey. The responder was ask to provide their best response to the four questions, with the understanding that their response in no way obligated their program or state to request recognition by NELAP.

Responses were obtained from 56 laboratory officials. Two responses were obtained from Texas and Washington since the responsibility for environmental laboratory accreditation resides within two different agencies in these states. Responses were eventually received from all 50 states, the District of Columbia (DC), Northern Mariana Islands (MP), Virgin Islands (VI), and Puerto Rico (PR). No response was obtained form federal agencies (Department of Interior, Nuclear Regulatory Commission, Army Corp of Engineers, Department of Energy, or the National Institute of Standards and Technology) or from laboratory officials in Guam (GU), or American Samoa (AS).

NELAC SURVEY RESULTS

Question 1: Does your environmental laboratory certification program intend to request recognition by NELAC?

- 40 Yes¹
- 2 No (ND, SD)
- 14 Not sure (AK, AZ, DE, MD, MI, MO, NC, NV, TX, TX, VT, WV, WY, VI)
- 2 No response (GU, AS)

Question 2: When will your laboratory certification program be ready to request recognition by NELAC?

- 9 As soon as possible (MN, IL, HI, WA, FL, NY, UT, CT, VA)
- 13 Before Oct 98 (AR, GA, IN, KS, MA, ME, NE, NH, NJ, NM, OH, OK, MP)
- 21 After Oct 98²
- 4 Not sure (PR, WV, WY, VI)
- 11 No response (AZ, DE, GU, MD, MI, NC, ND, NV, SD, VT, AS)

Question 3: Will legislative or statutory changes be needed before requesting recognition by NELAC?

- 32 Yes
- 14 No
- 8 Unknown
- 4 No response

Question 4: Will regulations or administrative rules need to be changed before requesting recognition by NELAC?

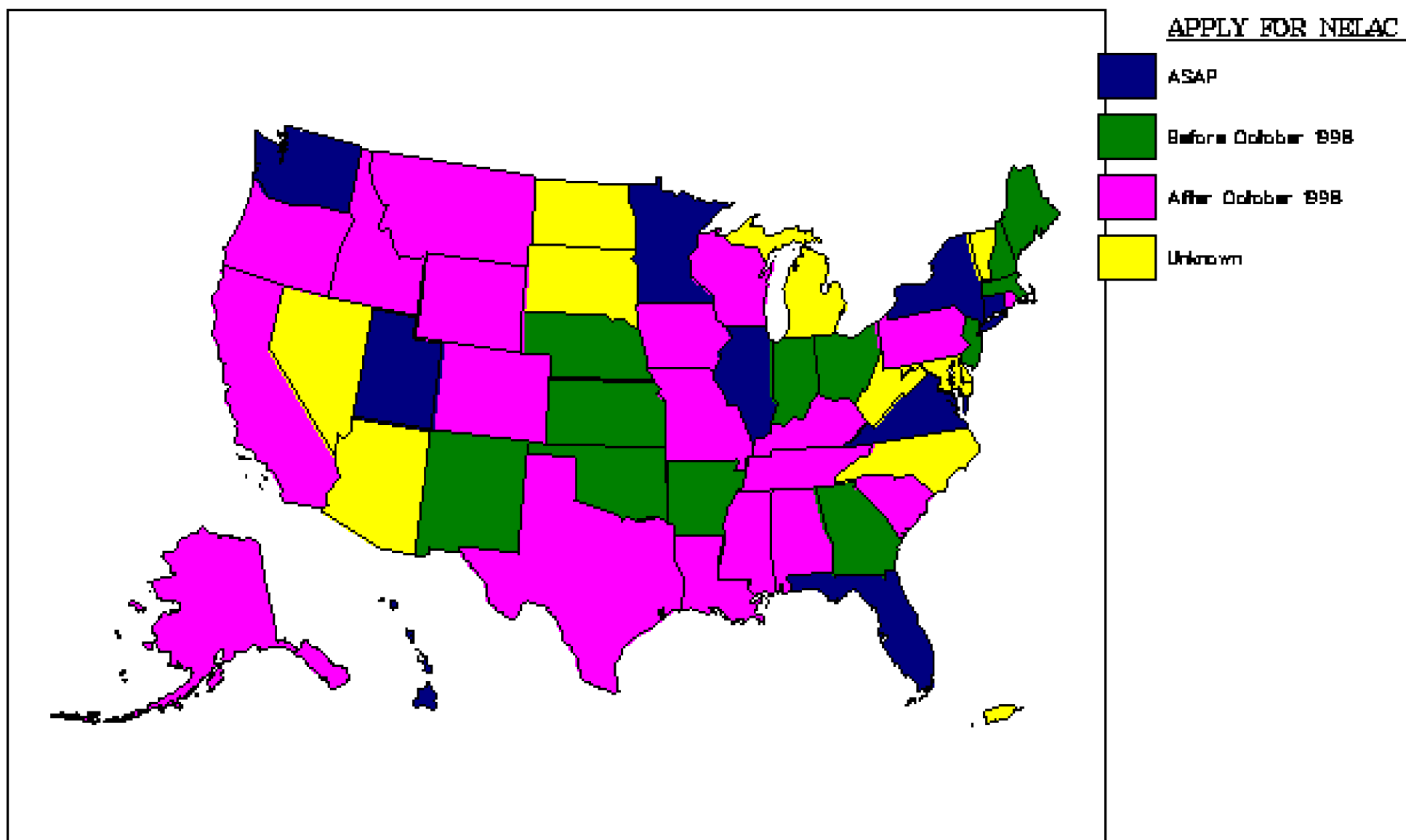
- 42 Yes
- 4 No
- 8 Unknown
- 4 No response

¹ (AL, AR, CA, CO, CT, DC, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, ME, MN, MP, MS, MT, NE, NH, NJ, NM, NY, OH, OK, OR, PA, RI, SC, TN, UT, VA, WA, WA, WI, PR)

² (AK, AL, CA, CO, IA, ID, DC, LA, MO, MS, MT, KY, OR, PA, RI, SC, TN, TX, TX, WA, WI)

State's Intention to Apply for NELAC

14 July 1997



**NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE
MAY 1997 INTENT SURVEY SORTED BY STATE**

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
AK	Richard Barrett	Environmental Health Lab	Not Sure	After Oct 98	N	Y
AL	John Williford	Dept. Environ. Management	Y	After Oct 98	Y	Y
AR	Jeff Ruehr	Dept. of Pollution Control & Eco.	Y	Before Oct 98	Unknown	Unknown
AS				No Response		
AZ	Barbara Erickson	State Health Lab	Not Sure		Y	Y
CA	George C. Kulasingam	Dept. of Health Services	Y	After Oct 98	Y	Y
CO	Ron Cada	Dept. of Public Health and Env.	Y	After Oct 98	Y	Y
CT	Nicholas P. Macelletti	Dept. of Public Health	Y	ASAP	Y	N
DC	James Thomas	DC Bureau of Laboratories	Y	After Oct 98	Y	Y
DE	Harry Otto	DNREC	Not Sure		Y	Y
FL	Stephen Arms	Dept. of Health & Rehab. Serv.	Y	ASAP	N	Y
GA	H. Lanford	Enviro. Prot. Div.	Y	Before Oct 98	N	Y
GU				No Response		
HI	Wanda Chang	Dept. of Health	Y	ASAP	Unknown	Unknown
IA	George M. Breuer	State Hygienic Lab	Y	After Oct 98	Unknown	Y
ID	Richard Hudson	Div. of Heath	Y	After Oct 98	Y	Y
IL	Jim Shaw	Illinois EPA	Y	ASAP	N	N
IN	Philip Zillinger	Dept. of Health	Y	Before Oct 98	Y	Y

Attachment 3

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
KS	Aurora Shields	Dept. of Health & Environment	Y	Before Oct 98	N	Y
KY	Gleason L. Wheatley	Dept. of Environmental Protection	Y	After Oct 98	Y	Y
LA	Louis R. C. Johnson	DEQ	Y	After Oct 98	Y	Y
MA	Ann Marie Allen	Dept. of Environmental Protection	Y	Before Oct 98	N	Y
MD	Marlene Patilo	Dept. of Environment	Not Sure		Y	Y
ME	Michael C. Sodano	Hlth. & Env. Test Lab, DOH	Y	Before Oct 98	Unknown	Y
MI	George Jackson	Dept. Of Environmental Quality	Not Sure		Y	Y
MN	Pauline Bouchard	Dept. of Health	Y	ASAP	Y	Y
MO	Connie Van Dyke	Div. of Environmental Quality	Not Sure	After Oct 98	Y	Y
MP	K. Yuknavage	DEQ	Y	Before Oct 98	Unknown	Unknown
MS	Phil Bass	DEQ	Y	After Oct 98	Y	Y
MT	Ann Weber	Dept. of Health & Env. Services	Y	After Oct 98	Y	Y
NC	John C. Sheats	State Lab. of Public Health	Not Sure		Y	Y
ND	Errol Erickson	DOH, Div. of Chemistry	N			
NE	John Blosser	NEDOH	Y	Before Oct 98	Y	Y
NH	Charles N. Dyer	Dept. of Environmental Services	Y	Before Oct 98	Unknown	Y
NJ	Joseph F. Aiello	New Jersey Dept. of Environmental Protection	Y	Before Oct 98	N	Y
NM	Barbara Giesler	New Mexican Environmental	Y	Before Oct 98	Y	Y

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
NV	P. Powning	DOH	Not Sure		N	Y
NY	Kenneth W. Jackson	DOH	Y	ASAP	N	N
OH	Gerry Ioannides	Ohio Environmental Protection Agency	Y	Before Oct 98	N	N
OK	Judy Duncan	DEQ	Y	Before Oct 98	Unknown	Y
OR	Richard Gates	Dept. of Environmental Quality	Y	After Oct 98	Y	Unknown
PA	Paul Baker	Dept. of Environmental Protection	Y	After Oct 98	Y	Y
PR	Reynaldo Matas	Environ. Quality Board Lab	Y	Not Sure	Y	Y
RI	Debra Dehmel	Dept. Enviro. Mgt.	Y	After Oct 98	Y	Y
SC	Daphne Neel	DHEC	Y	After Oct 98	Y	Y
SD	Michael Smith	SD Dept of Heath	N			
TN	Charlie Mickel	TN Dept. of Health	Y	After Oct 98	Y	Y
TX	Carol V. Batterton	TNRCC	Not Sure	After Oct 98	Y	Y
TX	David Maserang	Texas Dept. of Health/ Drinking Water	Not Sure	After Oct 98	Y	Y
UT	Dave Mendenhall	Utah Dept. of Health	Y	ASAP	N	Unknown
VA	J. Pearson	Div Consolid Labs	Y	ASAP	N	Y
VI	Norbert Mantor	Public Health Lab	Not Sure	Not Sure	Y	Y
VT	William Mills	Dept. of Health	Not Sure		Y	Unknown
WA	Cliff J. Kirchmer	Dept. of Ecology	Y	ASAP	N	Unknown

Attachment 3

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
WA	Dave Bingham/ George Hilton	Dept. of Health/ Drinking Water Certification	Y	After Oct 98	N	Y/N
WI	A. Sotomayor	DNR	Y	After Oct 98	Y	Y
WV	Charlotte Billingsley	WY Labs	Not Sure	Not Sure	Y	Y
WY	Ed Mock	DEQ	Not Sure	Not Sure	Unknown	Unknown

**NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE
MAY 1997 INTENT SURVEY SORTED BY DATE**

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
CT	Nicholas P. Macelletti	Dept. of Public Health	Y	ASAP	Y	N
FL	Stephen Arms	Dept. of Health & Rehab. Serv.	Y	ASAP	N	Y
HI	Wanda Chang	Dept. of Health	Y	ASAP	Unknown	Unknown
IL	Jim Shaw	Illinois EPA	Y	ASAP	N	N
MN	Pauline Bouchard	Dept. of Health	Y	ASAP	Y	Y
NY	Kenneth W. Jackson	DOH	Y	ASAP	N	N
UT	Dave Mendenhall	Utah Dept. of Health	Y	ASAP	N	Unknown
VA	J. Pearson	Div Consolid Labs	Y	ASAP	N	Y
WA	Cliff J. Kirchmer	Dept. of Ecology	Y	ASAP	N	Unknown
AR	Jeff Ruehr	Dept. of Pollution Control & Eco.	Y	Before Oct 98	Unknown	Unknown
GA	H. Lanford	Enviro. Prot. Div.	Y	Before Oct 98	N	Y
IN	Philip Zillinger	Dept. of Health	Y	Before Oct 98	Y	Y
KS	Aurora Shilds	Dept. of Health & Environment	Y	Before Oct 98	N	Y
MA	Ann Marie Allen	Dept. of Environmental Protection	Y	Before Oct 98	N	Y
ME	Michael C. Sodano	Hlth. & Env. Test Lab, DOH	Y	Before Oct 98	Unknown	Y
MP	K. Yuknavage	DEQ	Y	Before Oct 98	Unknown	Unknown
NE	John Blosser	NEDOH	Y	Before Oct 98	Y	Y
NH	Charles N. Dyer	Dept. of Environmental Services	Y	Before Oct 98	Unknown	Y

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
NJ	Joseph F. Aiello	New Jersey Dept. of Environmental Protection	Y	Before Oct 98	N	Y
NM	Barbara Giesler	New Mexican Environmental	Y	Before Oct 98	Y	Y
OH	Gerry Ioannides	Ohio Environmental Protection Agency	Y	Before Oct 98	N	N
OK	Judy Duncan	DEQ	Y	Before Oct 98	Unknown	Y
AK	Richard Barrett	Environmental Health Lab	Not Sure	After Oct 98	N	Y
AL	John Williford	Dept. Environ. Management	Y	After Oct 98	Y	Y
CA	George C. Kulasingam	Dept. of Health Services	Y	After Oct 98	Y	Y
CO	Ron Cada	Dept. of Public Health and Env.	Y	After Oct 98	Y	Y
DC	James Thomas	DC Bureau of Laboratories	Y	After Oct 98	Y	Y
IA	George M. Breuer	State Hygienic Lab	Y	After Oct 98	Unknown	Y
ID	Richard Hudson	Div. of Heath	Y	After Oct 98	Y	Y
KY	Gleason L. Wheatley	Dept. of Environmental Protection	Y	After Oct 98	Y	Y
LA	Louis R. C. Johnson	DEQ	Y	After Oct 98	Y	Y
MO	Connie Van Dyke	Div. of Environmental Quality	Not Sure	After Oct 98	Y	Y
MS	Phil Bass	DEQ	Y	After Oct 98	Y	Y
MT	Ann Weber	Dept. of Health & Env. Services	Y	After Oct 98	Y	Y
OR	Richard Gates	Dept. of Environmental Quality	Y	After Oct 98	Y	Unknown

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
PA	Paul Baker	Dept. of Environmental Protection	Y	After Oct 98	Y	Y
RI	Debra Dehmel	Dept. Enviro. Mgt.	Y	After Oct 98	Y	Y
SC	Daphne Neel	DHEC	Y	After Oct 98	Y	Y
TN	Charlie Mickel	TN Dept. of Health	Y	After Oct 98	Y	Y
TX	David Maserang	Texas Dept. of Health/ Drinking Water	Not Sure	After Oct 98	Y	Y
TX	Carol V. Batterton	TNRCC	Not Sure	After Oct 98	Y	Y
WA	Dave Bingham/ George Hilton	Dept. of Health/ Drinking Water Certification	Y	After Oct 98	N	Y/N
WI	A. Sotomayor	DNR	Y	After Oct 98	Y	Y
PR	Reynaldo Matas	Environ. Quality Board Lab	Y	Not Sure	Y	Y
VI	Norbert Mantor	Public Health Lab	Not Sure	Not Sure	Y	Y
WV	Charlotte Billingsley	WY Labs	Not Sure	Not Sure	Y	Y
WY	Ed Mock	DEQ	Not Sure	Not Sure	Unknown	Unknown
AZ	Barbara Erickson	State Health Lab	Not Sure		Y	Y
DE	Harry Otto	DNREC	Not Sure		Y	Y
MD	Marlene Patilo	Dept. of Environment	Not Sure		Y	Y
MI	George Jackson	Dept. Of Environmental Quality	Not Sure		Y	Y
NC	John C. Sheats	State Lab. of Public Health	Not Sure		Y	Y
ND	Errol Erickson	DOH, Div. of Chemistry	N			

Attachment 3

STATE	CONTACT	AGENCY	INTENT TO APPLY	DATE	STATUTE OR LAW REVISION	RULE OR REG REVISION
NV	P. Powning	DOH	Not Sure		N	Y
SD	Michael Smith	SD Dept of Heath	N			
VT	William Mills	Dept. of Health	Not Sure		Y	Unknown
AS				No Response		
GU				No Response		

COMMENTS FROM ILLINOIS EPA**IL-1 Comment:**

The NELAP National Data Base does not exist, it needs to be up and running as soon as possible.

Response:

The Ad Hoc Database Committee has developed a conceptual format for the NELAP database. They estimate that the database could be up and running by Fall of 1998, which should coincide with initial NELAP accreditations.

IL-2 Comment:

Enforcement/Due Process issue needs resolution.

Response:

Each state will continue to enforce their regulations under the current system. If a state has specific due process procedures, then those would be followed by that state.

IL-3 Comment:

Need clarification of the USEPA's Regions' role and ability to obtain resources for NELAP implementation. Other Regional issues in order of priority are:

- ◆ *The Regions' role in evaluation of State laboratories, State Accrediting Authorities and USEPA/other federal laboratories needs to be defined;*
- ◆ *Oversight of the Region's role by the NELAP Office;*
- ◆ *Consistency in implementation between the Regions;*
- ◆ *Regions' utilization of Contractors (i.e., potential conflicts-of-interest);*
- ◆ *Regional capability to fulfill their NELAP role; and*
- ◆ *Regions' lack of FTEs for NELAP.*

Response:

The USEPA Regional staff may be included in the assessment of an accrediting authority's program or the accreditation of a state laboratory as a member of the NELAP assessment team. Requirements for the NELAP assessment team are outlined in Section 6.9.1 of the

chapter on Accrediting Authorities. This section calls for the assessment team to consist of at least one full-time employee of EPA and one full time employee of a territory, state, or other federal agency laboratory accreditation program. The standards do not specify whether or not the EPA employee must be a Regional or Headquarters employee. This issue will be managed internally within EPA.

In order to assure consistency among assessment teams, there are qualifications for team members specified in Section 6.9.1(e). The Accrediting Authority Review Board also has responsibility to monitor EPA to assure that NELAC standards are being followed consistently. The Ad Hoc Transition Committee also recommends that checklists be developed for use by assessment teams conducting technical reviews of applications and on-site program audits. At this time, there are no plans to use contractors for the audit function.

USEPA has established the NELAP program office at EPA with a budget of \$300,000. Recently, Deputy Administrator Hansen confirmed EPA's commitment to NELAC.

Although specific FTE's have not been designated at the Regional level for NELAP implementation, it may be possible to provide resources through reallocation of existing resources.

IL-4 Comment:

When will NELAP be ready to start recognizing State Accrediting Authorities? States need to know when NELAP will be ready to start recognizing State Accrediting Authorities to aid in their planning for rule making and legislation.

Response:

The Ad Hoc Transition Committee recommends that NELAP begin accepting applications from accrediting authorities in October 1997. Applications received by December 1, 1997 will be processed simultaneously with a target date of June 15, 1998 for approval of accrediting authorities. See timelines on Attachments 1 and 2.

IL-5 Comments:

No draft NELAP implementation plans currently available from the NELAP Office or the NELAC Implementation Committee.

Pilot Program (PP) not clearly defined or how the PP relates to nation-wide implementation.

A decision needs to be made on whether NELAP implementation is going to be rolled out by USEPA Programs (i.e., SDWA first).

Response:

The recommended implementation plan is described in the body of this report and specifically in Attachments 1 and 2. NELAC will cover all EPA programs, not one program at a time. A pilot program per se, is not envisioned at this point.

IL-6 Comment:

States who are first accredited by NELAP could be overloaded with applications (no present plans to consider this impact).

Response:

The recommendations of the Ad Hoc Committee with regard to simultaneous approval of accrediting authorities and simultaneous issuance of initial accreditations will allow for management of accrediting authorities' workloads.

IL-7 Comments:

PBMS being held up within USEPA. PBMS needs to be finalized and have consistency of implementation across the various USEPA programs.

Response:

This issue is outside the scope of the Ad Hoc Transition Committee. Note, however, that the EMMC Policy Council has committed to have PBMS implementation plans developed by September 30, 1997.

IL-8 Comment:

The NELAC fields-of-testing structure needs to be finalized.

Response:

See Chapter One for details.

IL-9 Comment:

USEPA programs need to adopt and utilize the NELAC Quality System standard as a basis for their internal/programmatic quality systems for environmental laboratories. Without this NELAP will be unable to meet one of its original goals.

Response:

EPA currently has no intention to mandate the NELAC standards. All EPA Offices have, however, participated in the development and/or review of the standards.

IL-10 Comment:

The NELAC PT standards need to be finalized and the NELAP PT program made operational ASAP.

Response:

The Proficiency Testing Chapter will be presented for final adoption at NELAC III. The Ad Hoc Committee has recommended an interim approach to proficiency testing while the NELAP approved program is being established.

IL-11 Comment:

Assure redundant and contradicting language is removed from the standards (e.g., Chapter 4). Have not seen much progress on this since verbal commitments were made at the February 3-5 Interim Meeting.

Response:

The Ad Hoc Coordinating Committee began reviewing draft standards in late May for the purpose of identifying and removing conflicting and redundant language prior to voting at NELAC III.

IL-12 Comment:

On-Site audit checklists need to be developed and made available (as required in Chapter 3).

Response:

The Ad Hoc Transition Committee has recommended that audit checklists be developed by June 1998.

IL-13 Comment:

NELAC Chapter 4 needs to clarify accreditation statuses.

Response:

A revised version of Chapter 4 will be available at NELAC III.

IL-14 Comment:

The assessor training program needs to be defined and finalized.

Response:

EPA has developed a draft assessor manual. The Ad Hoc Transition Committee recommends that the assessor training program be completed by June 1998.

IL-15 Comment:

The biggest impediment I perceive, is the lack of commitment (at least as far as I know) on the part of some governmental agency(s) to put up an appropriate amount of "seed money" to get this program off of the ground. Of course, the funds to establish a training program/curriculum for the laboratory inspectors/evaluators are probably

needed as the highest priority.

Response:

See response to Illinois IL-3.

**COMMENTS FROM THE STATE OF CALIFORNIA
DEPARTMENT OF HEALTH SERVICES**

CA-1 Comment:

The format and requirements of this proposed program are oriented towards the large-scale full-service commercial laboratories where detailed documentation and record keeping requirements are crucial and the most highly qualified technical staff are necessary. The status of the small but essential operator-run wastewater and drinking water treatment plant laboratories in our program needs to be addressed and included in NELAC. These laboratories generate test results for process control and essential monitoring requirements on a routine basis. In most cases, degreed analysts are not available at these facilities; however, well-trained, experienced analysts conduct the tests.

If this issue remains unresolved, the accreditation authorities (states) approved by NELAC may have to administer multi-level accreditation programs within their jurisdictions in order to support their in-state regulatory programs relying on such small systems laboratories.

Response:

The application of NELAC standards to small laboratory operations is addressed in Section 1.1.4 of the Policy and Structure Chapter. Specifically this section states,

“All laboratory operations subject to NELAC standards are expected to generate data of known quality and maintain the quality systems required to generate quality data. However, NELAP recognizes that some laboratory operations have some unique characteristics that differentiate them from other operations. The NELAC standards have addressed these issues by allowing some flexibility in meeting the requirements for personnel (Section 5.4.2, Section 5.6) and their credentials (Section 4.1.1).”

Each state must evaluate their own laboratories to determine if application of NELAC standards across all laboratories is appropriate. If all laboratories within a state are to be included, the standards will allow for some flexibility in addressing the small labs. Some states may opt for a dual program that handles small one-person laboratories outside the scope of NELAC.

CA-2 Comment:

NELAC apparently has not addressed the issue of State-specific requirements, e.g., special monitoring requirements, data acceptance criteria, Shellfish Sanitation, Pesticide Residues in Food. Will the needs be addressed or will the States need to add another “tier” for the specific requirements?

Response:

Section 1.9.2 of the Policy and Structure Chapter allows the inclusion of state supplemental requirements. This section states “any supplemental accreditation requirements essential to meet the specific needs of an accrediting authority would be added at the method specific or analyte level, and must be approved by NELAP and made available to all NELAC participants.”

However, the Ad Hoc Transition Committee has serious concerns that excessive state supplemental requirements will jeopardize reciprocity which is a basic premise of NELAC. NELAC standards were conceived and developed to be inclusive of all media and programs regulated by EPA. Additional state regulations that include other media and programs would be outside the scope of the national program. There will be additional discussion on this topic at NELAC III.

CA-3 Comment:

When the NELAC and State requirements differ, will there be exemptions to permit State requirements to prevail or will the most stringent requirement prevail?

Response:

In order to preserve reciprocity among the various NELAP accredited programs, NELAC requirements will prevail if a state is an approved accrediting authority.

CA-4 Comment:

CA ELAP is administered as a fully fee-supported program and the fee structure is established by state legislature. Currently, the present fees adequately fund the costs of staffing, PE, and mandated activities. If the scope of the program is increased by implementing NELAC, the fees may not cover the additional costs.

Response:

If California ELAP chooses to become a NELAP accrediting authority, it will be the responsibility of the state program to seek the necessary fee increases to fund any additional costs.

CA-5 Comment:

Resource requirements to administer NELAP, e.g., required number of assessors based on the number of laboratories, scope of accreditation (Fields of Testing), frequency of on-site visits, oversight of contract laboratories, performance evaluation studies, and enforcement actions, are not determinable at this time especially while the State is downsizing and imposing hiring freezes. With limits placed on staffing, adoption and implementation of NELAC requirements may be difficult.

Response:

Adoption and implementation of NELAC standards by states is not federally mandated. NELAC is a voluntary association of states, and federal agencies seeking to bring consistency and reciprocity to existing and future environmental laboratory accreditation programs. Each state must evaluate its own political and economic situation in determining whether to seek approval as a NELAP accrediting authority.

CA-6 Comment:

The cost of the PE studies from the PT providers will have to be borne by the laboratories. California's ELAP (as well as many other states) has benefited from the "free" studies provided by the USEPA for Drinking Water, Radiochemistry and Wastewater. This benefit has been passed on to the laboratories. The smaller laboratories may be impacted the most. NELAC needs to find a way to encourage the small laboratories to participate without adding a huge financial burden.

Response:

This issue is outside the scope of the Ad Hoc Transition Committee. EPA will shortly be publishing a Federal Register Notice (FRN) outlining the proposed plan to alter the current WS/WP PE program. EPA will respond to all comments received during the designated comment period. This committee recommends that the proper forum for this comment would be in response to the upcoming FRN.

CA-7 Comment:

Until NELAC has clearly defined the Fields of Testing and Sub-Groups, California's ELAP cannot predict the full impact on the State program. The implementation of NELAC standards may lead to a multi-level or tiered program to accommodate the small laboratories and the laboratories performing tests in the more unusual/exotic Fields of Testing, e.g., Bioassay, Asbestos, Pesticide Residue in Food, Shellfish Sanitation).

Response:

NELAC standards should be fully adopted at the NELAC III meeting in July which will then allow states to assess the impact on state programs. Chapter 6 on Accrediting Authorities allows states or other agencies to receive approval as an accrediting authority with up to two years to make changes in state statutes or regulations.

CA-8 Comment:

With on-going discussions about the inclusion of Performance Based Methods (PBMs), NELAC will have to consider development and implementation of both the Site visit process and the PE Studies.

Response:

The NELAC standards have been developed with the goal of including methods used under a Performance Based Measurement System (PBMS). This committee recommends that any comments on perceived weaknesses in the standards be directed to the appropriate standing committee.

CA-9 Comment:

The plans for the National Database are crucial to the operations of the State program. Data must be transferred electronically and on a timely basis for the States to be able to operate effectively and efficiently.

Response:

See response to Illinois EPA IL-1

COMMENTS FROM ARIZONA LABORATORY ASSOCIATION

ALA-1

Comment:

We know the PE committee is working on standards for the providers so we will not address those concerns here. Consistency between the providers is absolutely necessary.

- ◆ *PE's should be used as a tool **FOR** certification not **AS** CERTIFICATION (ALA is concerned NELAC may just be a glorified PE program). It is much more realistic for a certification to be based on an on-site audit and to have the PE program used more as a process audit. For example: Did the lab have acceptable corrective action? Is there documentation of steps taken for correction? Can the lab do a follow-up with another PE sample or are they out of luck until the next set comes out? Etc.*
- ◆ *How often will PE's be submitted? And what types: DW, WW, Toxicity?*
- ◆ *When will results be provided? Currently feedback is so slow, labs are unable to use the WP and WS as a useful tool.*
- ◆ *Will there be a corrective action procedure when a PE is missed? What will it consist of?*
- ◆ *Will any PE's be provided blind? A blind PE is an excellent way to assess laboratory quality and will minimize the perceived advantage large network labs have had with the PE program in the past.*
- ◆ *Cost? Cost has been an issue from the beginning of these PE discussions. Will the laboratories contract directly with the PE provider? Will the laboratories be provided the PE's by the state with the cost included in licensure fees?*
- ◆ *What about state specific PE's for state specific testing? How will they be handled?*

Response:

The criteria for NELAC proficiency testing (PT) is specified in Chapter 2 of the standards. These standards clearly state that "proficiency testing is not the sole criterion for determining accreditation status." The laboratory audit is also a major component of the accreditation process. The standards state that the accrediting authority will consider PT results along with the other elements. This committee will forward these comments to the PT committee for their consideration.

ALA-2 Comment:

Will there be a national standard for auditing? Will auditors be required to obtain course certification? What qualifications must they have?

Response:

The standards for conducting on-site audits of laboratories and the qualifications for lab auditors are covered in Chapter 3 of the NELAC standards. Each assessor must satisfactorily complete an approved assessor training program and take periodic update/refresher training as specified by NELAC.

ALA-3 Comment:

If enforcement action is necessary, who will be in charge and what are the procedures?

Response:

Enforcement action is solely the responsibility of the state or federal agency. Actions to be taken on accreditation status are detailed in Chapter 4 on Accreditation Process.

ALA-4 Comment:

Since EPA is promoting performance based testing, the on-site audit will be even more critical. Is performance based testing encompassed in the NELAC program?

Response:

See response to California, comment CA-6.

ALA-5 Comment:

Will NELAC be voluntary? We have members who only need to be licensed in Arizona and would not want to pay a higher fee because of NELAC.

Response:

State participation as an accrediting authority in NELAC is voluntary. In participating states, it is left to the state's discretion which laboratories are required to obtain NELAP accreditation.

COMMENTS FROM THE STATE OF ARIZONA

AZ-1 Comment:

Will EPA continue to monitor and fund the training program for the NELAC auditors - an ongoing process? Who will train the trainers?

Response:

EPA has committed to fund the development of the training manual and the curriculum. It is envisioned that training could be offered by the states or the private sector.

AZ-2 Comment:

Will EPA continue to audit the EPA regional laboratories and State reference laboratories. Will EPA continue to fund these activities?

Response:

EPA will continue to audit the Regional laboratories and at least one State laboratory.

AZ-3 Comment:

Arizona has no monies appropriated by state legislators to pay for:

- ◆ *Environmental PT samples for the State reference laboratories. Will EPA phase in NELAC requirements?*
- ◆ *Environmental laboratory audits for the State reference laboratories. Will EPA continue to fund these activities?*
- ◆ *Costs of litigation with laboratories deemed to be out of compliance with NELAC requirements. The Health Care Finance Authority (HCFA) has the authority and funding under the Clinical Laboratory Improvement Act of 1988 (CLIA) to pay for these costs. Does EPA and/or other Federal Agency, i.e. NIST have such authority and monies?*

Response:

EPA has no plans to require that state or private sector laboratories participate in NELAC. States must fund their own activities if they choose to implement NELAC.

AZ-4 Comment:

Reciprocity between states cannot be resolved until EPA takes the lead and gives the commitment to monitor and fund “Due Process” issues.

- ◆ *As the Accrediting Authority, Arizona may not agree to enter into reciprocity with another state for example, New York, which is required to revoke a license based on non-compliance with PT requirements, instead of using the PT results as a consultative and monitoring tool.*
- ◆ *Arizona may also not agree to enter into reciprocity with another state which may have serious problems with its on-site auditing procedures, for whatever reason, and the validity of their laboratories test results are in question.*

To suspend or revoke a laboratory’s license, in either case, would invite “Due Process” issues for the Accrediting Authority (Arizona). This will especially be the case if on-site audits were performed by out-of-state auditors or the entire training program of auditors should become an issue.

Response:

Reciprocity among NELAP accrediting authorities is essential for NELAC to succeed. Approved accrediting authorities will be operating under the same standards. Accrediting authorities will be granted up to two years to make modifications to state statutes and regulations after receiving approval as an accrediting authority. Therefore, issues concerning differences in programs should not arise to a significant degree.

Chapter 1 on Policy and Structure speaks to the responsibilities of primary and secondary accrediting authorities in Sections 1.6.2.3.1 and 1.6.2.3.2. In Section 1.6.3 on reciprocity, the standards recognize that legal requirements may prevent some secondary accreditors from recognizing the primary accreditation of a particular laboratory because of Legal decisions prior to the primary accreditation.

AZ-5 Comment:

Since the survival of the laboratory may depend on the success or failure of it’s PT, the following should be considered:

One vendor for all PT samples for the sake of consistency, appropriate

manufacture of study samples for the sake of accuracy and precision and identical statistical analysis of the results for the sake of limiting any adverse effect due to faulty analysis of the data.

Response:

See response to California CA-6.

AZ-6 Comment:

Data acquisition, extent of testing and analysis of the results by electronic means, from multiple providers, requires a tremendous amount of work and monies. It took HCFA about four years to bring the various PT providers on line (at least as far as I know). In the mean time, accrediting authorities had to deal with PT reports by mail.

Response:

See response above.

AZ-7 Comment:

NELAC provides financial benefits for large commercial laboratories. However, small to medium sized laboratories, small utility laboratories and industrial laboratories do not benefit from a national accreditation consortium.

- ◆ *In Arizona there may only be 10 to 15 large commercial laboratories that might be interested in reciprocity with other states.*
- ◆ *The cost of PT samples, the analysis of the data, maintenance of the records by NELAC and the extensive audits performed by NELAC to certify small laboratories, small utility laboratories and industrial laboratories, has not been determined and may prove to be excessively expensive.*
- ◆ *The current state environmental laboratory licensing program has worked very well for Arizona. We may also be forced to operate two licensing programs as explained below under “comments from Kansas”.*

Response:

The application of NELAC standards to small laboratory operations is addressed in Section 1.1.4 of the Policy and Structure Chapter. Specifically this section states,

“All laboratory operations subject to NELAC standards are expected to generate data of known quality and maintain the quality systems required to generate quality

data. However, NELAP recognizes that some laboratory operations have some unique characteristics that differentiate them from other operations. The NELAC standards have addressed these issues by allowing some flexibility in meeting the requirements for personnel (Section 5.4.2, Section 5.6) and their credentials (Section 4.1.1).”

Each state must evaluate their own laboratories to determine if application of NELAC standards across all laboratories is appropriate. If all laboratories within a state are to be included, the standards will allow for some flexibility in addressing the small labs. Some states may opt for a dual program that handles small one-person laboratories outside the scope of NELAC.

AZ-8 Comment:

Currently Arizona has an active and very successful fee supported training program. This program aids the Arizona licensed laboratories with the technical support by:

- ◆ *Updating them on the current state and federal regulations via facsimile and consultation by telephone. A toll free telephone number is available for their use.*
- ◆ *Providing workshops to train staff from the licensed laboratories.*
- ◆ *By facilitating round table discussions between regulators and the regulated community.*

If Arizona adopts NELAP, how will this training and technical support program be funded?

Response:

Nothing in the current NELAC standards would prohibit the state of Arizona from continuing to provide a state fee-based training program for laboratories.

COMMENTS FROM THE STATE OF COLORADO**CO-1 Comment:**

There will probably be a lack of coordination between legislative and executive branches of state government, as alluded to in the ASTPHLD minutes. Our governor and executive director will be unhappy if the legislation is introduced without us seeing and preparing for it.

Response:

NELAC has no plans to introduce state legislation or to interfere with the states' legislative process. Selected state legislators are scheduled to receive information packages and questionnaires concerning NELAC, and hopefully, this material will encourage dialogue between the executive and legislative branches. This same information will be distributed to the state governors.

CO-2 Comment:

Public laboratories may or not (?) need accreditation; however, if they do in order for their data to be utilized for regulatory or self-monitoring purposes, they will be unhappy with the costs. Shades of CLIA.

Response:

Each state's decision to seek approval as an accrediting authority should be carefully coordinated with potentially regulated laboratories. Many laboratories will be willing to bear the extra cost in order to receive NELAP accreditation. See response to Arizona AZ-7

CO-3 Comment:

There could still be a public/private fiasco on implementation, although it is a given that states will be the non-delegatable accrediting authority.

Response:

Accrediting authorities must be governmental organizations, either territories, state, or federal. Accrediting authorities may contract some laboratory accreditation functions in accordance with Section 6.3.3.1.2 of Chapter 6 on Accrediting Authorities. The accrediting authority cannot delegate authority for granting, maintaining, suspending, or revoking a laboratory's NELAP accreditation.

COMMENTS FROM THE STATE OF NORTH CAROLINA

NC-1 Comment:

Agreement on uniform standards among 50 state programs seems highly unlikely.

Response:

Over 40 states have already cooperated to develop and approve approximately 70% of the draft standards. We expect acceptance of the remaining standards in July.

NC-2 Comment:

Cost of participation; completely unknown.

Response:

NELAC is designed to be a state fee supported program. Once all of the final standards are in place, each participating state will be able to analyze the costs of the program and set their fee schedule accordingly.

NC-3 Comment:

Certification rules: Every state will have to completely amend rules for all certification programs.

Response:

In order to be approved as a NELAP accrediting authority, a state or federal agency must operate their program in accordance with NELAC standards. Following NELAP approval, an accrediting authority will have up to two years to make changes in statutes or rules.

NC-4 Comment:

Oversight: This will require a large bureaucracy, probably at EPA level. Will this work any more successfully than what we presently have?

Response:

NELAC is a voluntary association of state and federal agencies. The program oversight provided by EPA at present consists of only two FTEs. Because the states have worked well together providing support to this program on a voluntary basis, there is no need to establish a large bureaucracy at EPA.

NC-5 Comment:

Everything considered, we doubt that many laboratories in North Carolina have an interest in Interstate Approval.

Response:

See response to Colorado CO-2 and Arizona AZ-7,

COMMENTS FROM THE STATE OF HAWAII

HI-1 Comment:

Need to review/adopt NELAC.

Response:

The committee recommends that the first round of applications be submitted by December 1997. States will have the opportunity to review and adopt the standards up until that time, if they wish to be included in the initial group of approved NELAP accrediting authorities.

HI-2 Comment:

Insufficient personnel to implement full set of environmental areas.

Response:

NELAC is designed to be a state fee funded program. Any necessary additions to staff could be funded through state fees. If a state chooses not to increase fees the NELAC standards could be applied in specific areas, e.g., drinking water only.

HI-3 Comment:

Time needed for labs to read, digest, and implement anything new for NELAC.

Response:

It is up to each state to decide when and if to apply to be a NELAP accrediting authority. Readiness of labs in a given state may be a factor in determining when a state chooses to apply for NELAP recognition.

HI-4 Comment:

Need for funding or provisions in rules for program costs, e.g. EPA getting out of the PE program business.

Response:

NELAC is designed to be a state fee funded program. Some states may need statutory changes or rule revisions in order to fund their state program. State programs can be designed to require that laboratories pay for their own PT samples directly from the approved providers.

COMMENTS FROM THE STATE OF KANSAS**KS-1 Comment:**

Personnel Qualifications. Chapter 4.1.1 will not work for about 85% of the environmental laboratories in Kansas. Most of these facilities are municipalities and industries certified for a few parameters.

The exceptions given in Sections 4.1.1(i) and (j) will not alleviate the problem since the exceptions are restricted to municipal drinking water facilities, wastewater facilities and industrial wastewater facilities. The exceptions are also limiting in the type of analysis listed.

This section does not represent the reality in the state of Kansas, where we can find industries doing limited testing, not just for wastewater, but for other environmental programs as well. This section does not represent some of the municipalities which are doing limited testing which cover other types of analyses not listed in Section 4.1.1(h).

Response:

The revised version of Chapter 4 on Accreditation Process states in Section 4.1.1(i) that an individual can meet the personnel qualifications if he or she is a full time operator of a drinking water or sewage treatment plant holding a valid certificate of competency to operate that facility. Such approval shall be limited to the scope of that facility's permit, and the laboratory must also meet the proficiency testing and quality control requirements and possess the requisite experience. Section 4.1.1(j) also states that an employee of an industrial waste treatment facility with at least one year of experience under supervision in an environmental laboratory can meet the personnel qualifications for laboratory director. This approval applies to the examination of environmental samples taken within the facility for the scope of that facility's regulatory permit.

KS-2 Comment:

It will be a great challenge for a small laboratory to implement some of the requirements listed in Chapter 5. Some of these laboratories are testing as little as once a month or even once per quarter.

Response:

If a small laboratory has not previously used QA/QC procedures, then the requirements of Chapter 5 on Quality Systems will present an additional workload. However, most NELAC participants have agreed that it is necessary for all laboratories to meet the requirements of Chapter 5 in order to assure that all NELAP accredited laboratories produce data of comparable quality.

KS-3 Comment:

The cost of purchasing the Proficiency Testing studies is of great concern to every laboratory, including the state principal laboratory.

Response:

See response to California CA-6.

KS-4 Comment:

It may be difficult to justify an increase in requirements for environmental laboratories in the state of Kansas when new regulations adopting NELAC standards are introduced. Most of our environmental laboratories are not interested in uniform standards, since all their work is done within the state. It will be difficult to justify a change in regulations for them. The current Kansas regulations have worked very well for our state.

We are very concerned that if the NELAC standards are not simplified for the smaller laboratories doing limited testing, we may be forced to operate two programs. One that covers Kansas laboratories doing analysis in-state only, and another program which meets NELAP approval.

I think that other states voiced some of the same concerns, but so far, changes have not been made in the NELAC standards.

Response:

All laboratories subject to NELAC standards are expected to generate data of known quality and maintain the quality systems required to generate quality data.

Each state must evaluate their own laboratories to determine if application of NELAC standards across all laboratories is appropriate. If all laboratories within a state are to be included, the standards will allow for some flexibility in addressing the small labs. Some states may opt for a dual program that handles small laboratories outside the scope of NELAC.

Each state must evaluate its own political and economic situation in determining whether to seek approval as a NELAP accrediting authority.

COMMENTS FROM NEW ENGLAND CERTIFICATION OFFICERS (NECO)**NE-1 Comment:**

NECO feels strongly that implementation of NELAC standards must be conducted nationally and in a uniform manner.

Response:

The NELAC Ad Hoc Transition Committee has recommended that the initial round of approvals for NELAP accrediting authorities be issued simultaneously. Likewise, the Ad Hoc Transition Committee also recommends that the initial round of laboratory accreditations be done simultaneously. These simultaneous approvals will allow for workload management in the first round as well as enhancing uniformity and consistency in program implementation.

NE-2 Comment:

NECO believes that October, 1997 is too early for acceptance of applications from potential accrediting authorities. At this point there are too many questions regarding NELAC and what its implementation means for the states. We recommend that there be a longer period (possibly 1 year) following the adoption of standards for states to assess NELAC's potential impact and to consider what changes are necessary in a state's program in order for it to be compatible with NELAP.

Response:

Final NELAC standards will be adopted at NELAC III in July. States will have until December 1, 1997 to determine if they want to apply for NELAP recognition in the first round. States not in the first round will have the opportunity to apply at a later date. The Ad Hoc Transition Committee and NELAP Director feel that delaying implementation for a year following adoption of final standards would result in a loss of support for the program from federal and state government as well as the private sector.

NE-3 Comment:

Because of the effort required in each state to make legislative or regulatory changes, the NELAC standards must be in a form which is not likely to change much for some time to come. Accordingly, states need to have the final standards available in time for review prior to the decision to join NELAC or not. There is usually 1 month's time or less between the posting of proposed standards and a NELAC meeting. More time is needed to assess how these standards translate into program changes. We need to have the standards available now in order to be prepared for the annual meeting. Any necessary amendments can be proposed and voted on at the meeting.

Response:

Draft standards will be available on the EPA bulletin board by July 1, 1997. Following final adoption of NELAC III, states will have until December 1, 1997 to decide if they want to be in the initial round of approvals for NELAP accrediting authorities. States not in the first round will have the opportunity to apply for NELAP recognition at a later time. The Accrediting Authority Chapter also allows states up to two years to make statutory and regulatory revisions following approval as a NELAP accrediting authority.

NE-4 Comment:

At NELAC meetings, states with only one person in attendance are able to follow the proceedings of only one committee at a time. States need to be given equal opportunity to review all of the standards as a whole. NECO suggests that a summary of the proceedings of each committee be available each evening, and, if possible, during the day so that states could be aware of proposed changes before voting.

Response:

At NELAC III, all of the standards will be reviewed and any proposed changes explained at a general session prior to voting.

NE-5 Comment:

NECO believes that once all states have had a reasonable amount of time and opportunity to make a decision whether or not to apply to become a NELAC accrediting authority, those states which do decide to go with NELAC are to be evaluated equally.

All states which meet the initial deadline for application are to be evaluated and decisions regarding their status as accrediting authorities are to be made before any state is allowed to call itself NELAC recognized. The idea is to allow all interested states to be in the "starting gate" at the same time and to be NELAC recognized at the same time.

Response:

See response to NE-1. The Ad Hoc Transition Committee has recommended that the initial round of applications from potential accrediting authorities be processed and approved simultaneously.

NE-6 Comment:

NECO's position is that accrediting authorities are not to use the NELAC name or logo until other accrediting authorities in the initial application pool have received NELAC recognition. We propose that there be a uniform effective date for NELAC recognition. Laboratories are not to use the NELAC name or logo until the uniform effective date.

Response:

The Ad Hoc Transition Committee has recommended simultaneous approval of the initial round of accrediting authorities and laboratories. Accrediting authorities and labs would not be allowed to use the NELAP logo until the specified approval date.

NE-7 Comment:

NECO is concerned about the amount of support that NELAC will receive from the USEPA. What kind of help will be available during implementation and transition? Is there a central place for asking questions? A “help desk” would be a minimum expectation.

Response:

NELAP office staff will be available to answer questions regarding implementation. The “help desk” idea is excellent and will be given consideration.

NE-8 Comment:

Will NELAC recognition in all fields of testing be available initially or will there be a phase-in period with priority given to those programs such as drinking water which already have a certification program in place?

Response:

All fields of testing will be available initially.

NE-9 Comment:

How will EPA get its own programs recognized? Drinking water? Others?

Response:

The EPA Program Offices will make a presentation at NELAC III describing the process for implementation of the NELAC standards. These plans will vary depending on the nature of the program and the statutory authority.

NE-10 Comment:

Is there a provision for the acceptance of the credentials of current certification officers?

Response:

The On-Site Assessment Chapter specifies qualifications for state certification officers.

Flexibility in meeting those requirements are outlined in this chapter including the recognition of previous experience of the current certification officers.

NE-11 Comment:

If a state is NELAC-recognized as an accrediting authority, are all the labs within that state automatically part of NELAC?

Response:

A laboratory cannot be NELAP accredited unless it meets NELAC standards. It is possible, though unlikely, that any current state program exactly mirrors NELAP. Therefore, it is unlikely that any laboratories will automatically become NELAP accredited at the time the state receives approval as an accrediting authority.

NE-12 Comment:

What if no accrediting authority is available or able to certify a lab in a particular state? We need to ensure that NELAC-recognized states are not overloaded trying to inspect and certify labs in states which are not NELAC-recognized.

Response:

See Issues and Recommendations II in the main body of the report.

NE-13 Comment:

Is model legislative language available yet? Something that is presented from a national perspective may be easier to get through the state legislature.

Response:

The NELAC Implementation Committee is developing model state legislation. This should be available at NELAC III.

NE-14 Comment:

Do the NELAC standards ensure that the person responsible for day to day management of an accrediting authority's environmental laboratory accreditation program is knowledgeable enough to take responsibility for the program, understands laboratory issues and, above all, is able to deal with issues involving enforcement when a laboratory is found to be out of compliance or engaging in illegal practices?

Response:

The Accrediting Authority Chapter does not contain specific qualifications for management personnel in the state's program. This item will be brought to the attention of the Accrediting Authority Committee for their consideration.

NE-15 Comment:

If a state becomes an approved accrediting authority, may it accredit its own lab? If the accrediting authority is located in one department or agency within a state and the lab is in another department, may the accrediting authority certify that lab?

Response:

A state may accredit its own lab if it can demonstrate by organizational structure that the laboratory management and accreditation program management do not report to the same individual or that by policies and procedures conflicts of interest do not exist. If a state lab has an organizational conflict of interest with the accreditation program, it may seek accreditation through any other NELAP recognized accrediting authority.

NE-16 Comment:

If a state regulates contaminants not already regulated under federal program, is it possible that this would force labs to seek certification under a state's own program rather than NELAC? How does NELAP propose to approve supplemental accreditation?

Response:

States may request inclusion of state supplemental standards at the time they apply for NELAP approval as an accrediting authority. The NELAP Director must approve all requests for state supplemental standards.